MAY 1 6 2002

K014235

IMPLANT INNOVATIONS, INC.
A BIOMET COMPANY

Summary of Safety & Effectiveness

COMPANY:
Implant Innovations, Inc.
4555 Riverside Drive
Palm Beach Gardens, FL 33410

CONTACT:
Jacquelyn A. Hughes, RAC
Director, Regulatory Affairs & Quality Assurance
Telephone: 561-776-6819
FAX: 561-776-6852
E-mail: jhughes@*3i*mplant.com

DATE PREPARED:
December 21, 2001

NAME OF THE DEVICE:
OSSEOTITE NT™ Implant System
Classification: DZE Class III
Common Name: Endosseous Implant

PREDICATE DEVICES:
OSSEOTITE® Dental Implants and Accessories cleared for marketing via the following premarket notifications:

- K935544 for an acid-etched process to create the OSSEOTITE® Brand surface cleared on March 13, 1995,
- K980549 for a performance claim cleared on April 28, 1998,
- K983347 for a performance claim cleared on January 1, 1999, and
- K013570 for Instructions for Use changes cleared on December 18, 2001.

The OSSEOTITE NT™ Dental Implants taper feature is substantially equivalent to at least two currently marketed dental implants:

- Nobel Biocare USA, Inc. (Steri-Oss), Replace™ TPS Coated Implants cleared via K002475 on November 9, 2000, and the
- Friadent GmbH FRIALIT™-2 Stepped Screw Implant cleared via K994376 on March 24, 2000.

Color coding is substantially equivalent to the Nobel Biocare USA, Inc. (Steri-Oss), Replace™ TPS Coated Implants.

DEVICE DESCRIPTION:

Implant Innovation's dental implant systems include screw-form (i.e. threaded) titanium implants with a machined, external HEX to assist in placement and to provide anti-rotation features for the restoration. The OSSEOTITE® Brand implants have a special dual acid-etched treatment process to increase surface roughness.

The OSSEOTITE NT™ Dental Implants are tapered implants designed to mimic the shape and form of a natural tooth. The taper aspect ratio varies depending upon the length and diameter. The NT implants will be available in diameters of 3.25, 4.0, 5.0 and 6.0 mm and lengths of 8.5, 10.0, 11.5, 13.0 and 15.0 mm.

INDICATIONS FOR USE:

The OSSEOTITE NT™ Implant System is indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment to restore a patient's chewing function.

CONTRAINDICATIONS:

Placement of *3i* dental implants may be precluded by patient conditions that are contraindications for surgery.

3i implants should not be placed on patients where the remaining jaw bone is too diminished to provide adequate implant stability.

PERFORMANCE DATA:

Data consistent with the recommendations in the FDA guidance document *Information Necessary for Premarket Notification Submissions for Screw-Type Endosseous Implants*, December 9, 1996, mechanical testing of the implants demonstrated that the OSSEOTITE NT™ Dental Implants possess mechanical strength at least equivalent to the currently marketed OSSEOTITE® Dental Implants.

CONCLUSION:

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that OSSEOTITE NT™ Dental Implants and Accessories are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2002

Ms. Jeannette G. Dailey
Regulatory Affairs Manager
Implants Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K014235
Trade/Device Name: OSSEOTITE NT™ Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: March 26, 2002
Received: March 27, 2002

Dear Ms. Dailey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cucenite/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K014235

510(k) Number (if known): _____

Device Name: OSSEOTITE NT™ Implant System

Indications for Use:

OSSEOTITE NT™ Implant System is indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment to restore a patient's chewing function.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014235

Prescription Use: ✓ OR Over the Counter Use: _____
(Per 21 CFR 801.109)